EXHIBIT 1

Written Statement of Lawrence J Winikur, M.D.
Re: Michael R. Kennedy

I submit this written statement based on my review of records and information available to me pertaining to epidural steroid injections administered to Michael R. Kennedy and his subsequent treatment.

The listed individual received steroid injections on July 2, 2012, August 6, 2012, and August 27, 2012 by Randolph Y. Chang, M.D. at APAC Centers for Pain Management, located in Westchester, Illinois. Dr. Randolph Y. Chang, M.D. is an employee of APAC Centers for Pain Management.

Based on the information presently available the steroids injected into the above referenced individual was, or there is a reasonable basis to believe that they were, preservative free methylprednisolone acetate ("MPA") procured from an out of state compounding pharmacy known as New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC").

Qualifications

I am a physician licensed to practice medicine in Virginia. I obtained my Medical Degree from the Medical College of Virginia, Richmond, VA in 1988. I completed my residency in Anesthesiology and obtained advanced training in Anesthesiology and Pain Management at the Mayo Clinic in Rochester, NY in 1992. I have practiced in the field of Pain Management for 21years.

In my professional career I have worked as a physician, Hospital Staff Anesthesiologist, Pain Clinic Director, and Medical Director of a pain clinic. I currently work as the Medical Director of Piedmont Pain Medicine, PC in Danville, VA. As the owner of a clinic where epidural steroid injections are performed, where medications for such procedures are purchased and handled, where patient records are documented, where procedures and drugs are coded and billed, I practice under the same standard of care applicable to APAC Centers for Pain Management. Additionally, to the extent applicable, I am aware of the duty of reasonable care owed by APAC Centers for Pain Management. All opinions by me are offered to a reasonable degree of medical probability and/or probability within my field of expertise.

I am familiar with the applicable standard of care in Virginia and Illinois pertaining to and concerning the administration of sterile steroid injections into the indicated regions of patients' bodies. I personally have injected patients with sterile steroids on a regular basis over the past several decades. In my opinion, Westchester, Illinois is a similar community to Danville, Virginia. I have also been qualified to serve as an expert in the past.

Accordingly, I believe that I am competent to express opinions to a reasonable degree of medical certainty regarding the fields of Medicine, Anesthesiology, and Pain Management.

Parties

It is my understanding that APAC Centers for Pain Management is located in Westchester, Illinois. It is further my understanding that according to information compiled by the United States Food and Drug Administration, APAC Centers for Pain Management purchased vials of preservative free methylprednisolone acetate ("MPA") from an out of state

compounding pharmacy known as New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") during, at least, June-August 2012.

Information Reviewed

My statements are based on my background, education, training and experience as well as information taken from Mr. Kennedy's medical records from Dr. Randolph Y. Chang, M.D., APAC Centers for Pain Management, and other facilities in which Mr. Kennedy received treatment as a result of complications related to the steroid injections. I have also reviewed the relevant publically available information pertaining to NECC, including articles published in peer-reviewed journals and FDA and CDC materials relating to the issues in this case. For example, my review included:

a. July 17, 2001, American Society of Health-System Pharmacists report *Meningitis Deaths Linked to Drug Shortage* (Three deaths in the San Francisco area caused by bacterial meningitis stemming from epidural steroid injections with contaminated compounded steroids).

b. May 29, 2002, FDA Compliance Policy Guide, Sec. 460.200 *Pharmacy Compounding,* warning: "FDA believes that an increasing number of establishments with retail pharmacy licenses are engaged in the manufacturing and distributing unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act."

c. December 13, 2002 CDC report on Exophiala Infection from Contaminated Injectable Steroids Prepared by a Compounding Pharmacy – United States, July – November 2002 (North Carolina cases of fungal meningitis caused by epidural injections at outpatient pain management clinics, where improperly compounded medications were the source).

d. May 31, 2007 FDA Report: *The Special Risks of Pharmacy Compounding*

e. November 5, 2010 Summary Report of the American Society of Anesthesiologists (and others) addressing appropriate responses to periodic drug shortages.

f. 2010 FDA Video *FDA and Pharmacy Compounding*

Based upon that information, I understand the facts regarding this individual patient to be as follows:

July 2, 2012, August 6, 2012, and August 27, 2012, Dr. Yang performed cervical epidural steroid injection (ESI) procedures on Michael R. Kennedy at APAC Centers for Pain Management's facility, during which procedure Mr. Kennedy was administered, according to his medical records, NECC's preservative free MPA from one or more vials. One or more of the MPA vials used during the July 2, 2012, August 6, 2012, and August 27, 2012 procedures was drawn from vials that were part of one or more of the three lots of contaminated MPA vials that NECC recalled on or about September 26, 2012, due to fungal contamination traced back to NECC by the FDA and CDC.

Following the ESI procedures on July 2, 2012, August 6, 2012, and August 27, 2012, the fungus contaminated MPA caused Mr. Kennedy to sustain and suffer injury to his body. Mr.

Kennedy thereafter developed pain and other symptoms, including memory loss, bone pain, muscle pain, extreme problems urinating, hot and cold sweats, dizziness, nausea, lack of appetite, weakness, blurred vision, trouble lying down, joint pain, pain in the ribs, hips, neck and back, and rashes. Plaintiff's symptoms continued to deteriorate, forcing him to go to Good Samaritan Hospital for treatment. On October 13, 2012, Plaintiff underwent a lumbar puncture. On October 15, 2012, an MRI was performed on his lumbar spine. The lumbar puncture uncovered elevated protein levels and beginning on January 15, 2013, he was treated with anti-fungal medication prescribed by Edward Sherman, M.D., an infectious disease doctor. The course of medical care and treatment which followed from the contaminated injections required Plaintiff to be hospitalized or attended to at various out-patient facilities. Mr. Kennedy's medical care and treatment has required him to be hospitalized or attended to at various out-patient facilities during which he underwent numerous medical tests, including a lumbar puncture and diagnostic imaging. Many of his symptoms continue today.

NECC History

Based on information previously provided to me, I am aware of the following concerning NECC.

NECC began operations in June 1998. The first enforcement action against NECC began in April 1999, just 10 months after it obtained its license. The Massachusetts Board of Registration in Pharmacy (the "MA Board") filed a complaint stating that NECC was including blank prescriptions in its solicitations to doctors, in violation of state law.

In 2002, a physician reported to the FDA that at least five patients had become ill following epidural injections that contained NECC medications.

In July 2002, William Koch contracted bacterial meningitis after being injected with contaminated MPA compounded by NECC. Mr. Koch eventually died from complications related to the infection. In 2004, Mr. Koch's family sued the NECC and the medical providers who performed the injection. The case was later settled.

In August 2002, additional adverse events were reported to the FDA concerning patients who had contracted meningitis. The suspected source of the infections were epidural injections that contained methylprednisolone acetate compounded by NECC. The FDA investigated NECC following the adverse events and found that five of 16 vials were contaminated with bacteria. The investigators concluded "sample results revealed that the firm has sterility and potency issues with injectable steroid suspensions (betamethasone repository USP and methylprednisolone acetate USP)."

In December 2006, the FDA issued a Warning Letter to NECC. The letter details numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA's website for years. The FDA posted that letter under the heading "Significant Compliance Actions."

In 2011, the Colorado Board of Pharmacy issued a Cease and Desist letter to NECC as a result of distribution of non-patient specific compounded drugs to hospitals in Denver.

In September 2012, health officials identified an outbreak of fungal meningitis. Investigators traced the outbreak to medication compounded by NECC. To date, more than 700 people have been sickened by medications compounded by NECC and more than 60 people have died.

Dangers of Compounded Drugs

The risks of pharmacy compounding have been the subject of considerable public discussion in the pharmacy community and the medical community. Compounding pharmacies are not subject to the same FDA regulations as drug manufacturers, most importantly compounding pharmacies are not required to report adverse health events to the FDA so that the public and practitioners are accurately informed of and alerted to such events. Compounded drugs are not FDA approved and even more worrisome, there exact formulations are unknown. The FDA warned against using compounded drugs unless medically necessary for a specific patient's needs.

The American Society of Health System Pharmacists ("ASHP") has also played an active role in warning the pharmacy and medical communities of the risks of using compounded drugs. In 2010 the ASHP published the "ASHP Guidelines on Outsourcing Sterile Compounding Services." They also developed a "Contractor Assessment Tool" for healthcare organizations to use in conjunction with their guidelines. That document was developed to be used by health systems when deciding whether and from where they should purchase compounded medications.

The guidelines state that health systems should perform certain due diligence before purchasing drugs from compounders. For example, before buying compounded drugs, the purchaser should: (1) have an employee or agent visit the compounding pharmacy; (2) determine whether the compounding pharmacy has had product liability lawsuits filed against it; (3) determine whether the compounding pharmacy has ever recalled any of its compounded preparations; and (4) review regulatory surveys conducted of the compounding pharmacy's site, including copies of significant regulatory actions, among many other things.

Reasonable and Meritorius Cause for Filing

Based on my education, training and experience, and my review of the medical records, and aforementioned documents and information, it is my opinion to a reasonable degree of medical probability that the recognized standard of acceptable professional practice of medicine, specifically as it relates to the acquisition, storage and administration of sterile medications for injection in all medical practices and specialties in Westchester, Illinois and similar communities as it existed during the 12 month period preceding and including July and August 2012 would require Health Care Providers, such as APAC Centers for Pain Management and its medical director and managers, to exercise due care in selecting, procuring and administering steroids for injection into patients. The standard of care and the duty of reasonable care require that physicians and clinics or procurers of pharmaceuticals, like APAC Centers for Pain Management, must: (1) understand the source of drugs injected in ESI's, (2) procure such drugs from FDA-regulated and approved sources, and (3) only use compounded drugs under certain circumstances.

It is my opinion that APAC Centers for Pain Management was careless and negligent and breached the standard of care in one or more of the following respects:

a) APAC Centers for Pain Management procured injectable steroids from NECC, for the purpose of injecting those medications into the spines of patients for profit, without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;

b) APAC Centers for Pain Management failed to visit NECC's facilities before procuring spinal injection medicines from that company;

c) APAC Centers for Pain Management failed to investigate and exercise sufficient due diligence before administering injectable steroids procured from NECC, including its failure to investigate or inquire concerning NECC's compounding practices;

d) APAC Centers for Pain Management failed to determine whether NECC had a history of recalling compounded medications before procuring spinal injection medicines from that company;

e) APAC Centers for Pain Management failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring spinal injection medicines from that company;

f) APAC Centers for Pain Management failed to determine whether NECC had a history of adverse events, complaints, and/or product liability suits before procuring spinal injection medicines from that company;

g) APAC Centers for Pain Management failed to keep abreast of the dangers of sterile compounding and recommended and practices relating to acquisition and administration of compounded sterile products, and especially preservative free versions of medications such as the MPA involved in this case;

h) APAC Centers for Pain Management failed to heed and apply prudent and recommended and practices;

i) APAC Centers for Pain Management purchased compounded injectable steroids from an unaccredited compounding pharmacy;

j) APAC Centers for Pain Management failed to implement policies and procedures that would prevent procurement of purportedly sterile injectable medications from an out-of-state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of adverse events and product liability suits;

k) APAC Centers for Pain Management injected steroids into Mr. Kennedy's neck without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with pathogens;

l) Dr. Chang injected steroids into Mr. Kennedy's neck during ESI procedures without taking reasonable steps to determine whether the medication administered was safe and suitable for injection into Mr. Kennedy;

m) APAC Centers for Pain Management failed to properly inform Mr. Kennedy prior to administration the medication being injected into him was not manufactured by an FDA

approved manufacturer, but rather was acquired from an out of state compounding pharmacy that is not licensed by or inspected by the FDA; and

n) APAC Centers for Pain Management failed to properly and fully advise Mr. Kennedy of the material risks and dangers inherent and potentially involved in using NECC's compounded preservative free MPA instead of other available medication alternatives when obtaining informed consent for the ESI procedure.

In addition, APAC Centers for Pain Management deviated from the standard of care by failing to notify Mr. Kennedy of the risks and benefits associated with the proposed manner of treatment and of the alternatives to such treatment. APAC Centers for Pain Management was negligent in failing to appropriately and adequately obtain the informed consent from Mr. Kennedy, prior to performing the ESI injection.

It is further my opinion that the recognized standard of acceptable professional practice in Medicine and Pharmacy in Westchester, Illinois and similar communities during 2012 would require a clinic, and its medical directors and managers, to either: (1) consult with and rely upon a qualified licensed pharmacist or hospital pharmacy department to select the source of injectable steroids, to determine whether or not to purchase injectable steroids from a particular compounding pharmacy and to determine whether a particular compounding pharmacy is a safe and reliable supplier of sterile injectables; or (2) require the medical director and managers to undertake a sufficient and appropriate investigation of the source of injectable steroids and in the event the medical director decided to procure injectable steroids from a compounding pharmacy to determine that the pharmacy is a safe and reputable supplier of injectable steroids. Such due diligence should, at a minimum, include a site visit and/or background investigation consistent with the guidelines published by the American Society of Health System Pharmacists.

It is further my opinion that the entities and/or persons who decided to purchase preservative-free methylprednisolone acetate ("MPA") from NECC for administration to patients fell below the applicable standard of care as that standard of care as it existed in Westchester, Illinois and similar communities during 2012 in the event they did not consult with and rely upon a qualified pharmacist to procure and select an appropriate source of injectable steroids or exercise appropriate due diligence by conducting a site visit and appropriate investigation of NECC.

The aforesaid breaches of the standard of care caused the injuries, damages and losses sustained by Mr. Kennedy. Mr. Kennedy's injuries were due to the negligent and careless acts and omissions of APAC Centers for Pain Management.

Based upon the information available to me from the medical records and other material concerning the care and treatment of Michael R. Kennedy, there is a reasonable and meritorious cause for filing an action against APAC Centers for Pain Management, and any other persons or entities responsible for the administration of MPA to Mr. Kennedy and/or for the procurement of the subject steroids from NECC, including its managers and owners. It is my opinion that to the extent the medical director and manager of APAC Centers for Pain Management made the decision to purchase the subject steroids from NECC without the involvement of and reliance upon a pharmacist, there is a reasonable and meritorious cause for filing an action against the medical director and manager of APAC Centers for Pain Management.

Finally, based on the information available to me there are facts material to the resolution of the case that cannot be reasonably ascertained from the medical records and information provided to me. Despite the absence of this information, there is a reasonable and meritorious cause for filing an action against APAC Centers for Pain Management along with any other entities responsible for the procurement of the subject steroids from NECC.

Lawrence J. Winkler, M.D
Medical Director, Piedmont Pain Medicine, PC

December 18, 2013
Date